

**I Claim:**

1. A method for detecting prostate cancer in a subject comprising measuring kallikrein 11 and prostate specific antigen (PSA) in a sample from the subject.
2. A method for detecting prostate cancer in a subject comprising:
  - 5 (a) determining the amount of kallikrein 11 in a sample from the subject;
  - (b) determining the amount of PSA in the sample;
  - (c) mathematically combining the results of step (a) and step (b); and
  - (d) relating the combination to the presence of prostate cancer.
3. A method as claimed in claim 1 or 2 wherein in step (a) kallikrein 11 is determined using antibodies that specifically bind to kallikrein or a part thereof.
- 10 4. A method as claimed in claim 1, 2, or 3 wherein in step (b) the PSA is measured using antibodies that specifically bind to PSA or a part thereof.
5. A method as claimed in claim 2 wherein in step (a) kallikrein 11 is determined in the sample by
  - 15 (a) incubating a sample from the subject with a first antibody that specifically binds kallikrein 11 which is directly or indirectly labeled with a detectable substance, and a second antibody that specifically binds kallikrein 11 which is immobilized; and
  - (b) detecting the detectable substance thereby determining kallikrein 11 in the sample.
6. A method as claimed in claim 2, 3, 4, or 5 wherein in step (b) total PSA is determined in the sample.
- 20 7. A method as claimed in any of claims 2 to 6 wherein the combination is a ratio of kallikrein 11 to total PSA, or the inverse thereof.
8. A method as claimed in any preceding claim which further comprises the step of determining the % free PSA and relating the combination and % free PSA to the presence of prostate cancer.
9. A method as claimed in any preceding claim wherein the combination is compared to a predetermined standard.
- 25 10. A method for distinguishing prostate cancer from benign prostatic hyperplasia (BPH) in a subject comprising determining the amount of kallikrein 11 contained in a sample from the subject, and relating the amount to the presence of prostate cancer or BPH in the subject.
11. A method as claimed in claim 10 wherein the kallikrein 11 is measured using antibodies that specifically bind to kallikrein 11 or a part thereof.
- 30 12. A method as claimed in claim 10 or 11 wherein the amount of kallikrein 11 in the sample is compared to an amount determined for a standard.
13. A method as claimed in claim 12 wherein the standard is an amount of kallikrein 11 associated with prostate cancer.
- 35 14. A method as claimed in claim 13 wherein an amount of kallikrein 11 in the sample greater than the standard is indicative of BPH.
15. A method as claimed in claim 12 wherein the standard is an amount of kallikrein 11 associated with BPH.
16. A method as claimed in claim 15 wherein an amount of kallikrein 11 in the sample lower than the

standard is indicative of prostate cancer.

17. A method for distinguishing prostate cancer from benign prostatic hyperplasia (BPH) in a subject comprising:

5 (a) determining the amount of kallikrein 11 contained in a sample from the subject;

(b) determining the amount of total PSA contained in the sample;

(c) mathematically combining the results of (a) and (b);

(d) relating the combination to the presence of BPH or prostate cancer.

18. A method as claimed in claim 17 wherein the combination is a ratio of kallikrein 11 to total PSA, or the inverse thereof.

10 19. A method as claimed in claim 17 or 18 wherein the kallikrein 11 is measured using antibodies specifically reactive with kallikrein 11 or a part thereof.

20. A method as claimed in claim 17, 18 or 19 wherein the PSA is measured using antibodies specifically reactive with PSA or a part thereof.

21. A method as claimed in any one of claims 17 to 20 wherein the combination is compared to a 15 combination for a standard.

22. A method as claimed in claim 21 wherein the standard is a combination associated with prostate cancer.

23. A method as claimed in claim 22 wherein a combination in the sample is greater than the standard is indicative of BPH.

20 24. A method as claimed in claim 21 wherein the standard is a combination associated with BPH.

25. A method as claimed in claim 24 wherein a combination in the sample lower than the standard is indicative of prostate cancer.

26. A method of any one of claims 17 to 25 further comprising determining the percentage of free PSA and correlating the percentage free PSA and the combination to the presence of prostate cancer or 20 BPH in the subject.

25 27. A method for determining the presence of BPH or prostate cancer in a subject comprising:

(a) providing a first binding agent that specifically binds to kallikrein 11;

(b) providing a second binding agent that specifically binds to PSA;

(c) contacting the first agent and second agent with the sample under a condition that allows 30 the formation of a first complex comprising the first agent and the kallikrein 11, and a second complex comprising the second agent and the PSA;

(d) determining the presence or amount of the first and second complexes;

(e) mathematically combining the amount of the first and second complexes; and

(f) relating the combination to the presence of BPH or prostate cancer.

35 28. A method as claimed in claim 27 wherein the combination is a ratio of the first complex to the second complex, or the inverse thereof.

29. A method of claim 27 or 28 wherein the binding agents are antibodies.

30. A method of claim 27 or 28 further comprising determining the percentage of free PSA and correlating the percentage free PSA and the combination to the presence of prostate cancer or BPH

in the subject.

31. A method of any preceding claim wherein the subject has total PSA between about 4-10 ng/ml.
32. A method of any preceding claim wherein the subject has total PSA less than 4 ng/ml.
33. A method of any preceding claim wherein the sample is a mammalian tissue sample.
- 5 34. A method of any preceding claim wherein the sample is a sample of human physiological fluid.
35. A method of any preceding claim wherein the sample is serum, seminal plasma, urine, or plasma.
36. A method of improving the accuracy of a diagnosis of prostate cancer comprising the steps of: a) performing a method of any of the preceding claims; and b) performing at least one of a test for free PSA and a digital rectal examination.
- 10 37. A method for screening prostate cancer by determining the ratio between kallikrein 11:total PSA in a subject's serum.
38. A method for differentiation between BPH or prostate cancer by determining the ratio between kallikrein 11:total PSA in a subject's serum.
39. A kit for determining the presence of BPH or prostate cancer in a subject, comprising a known amount of a binding agent that specifically binds to kallikrein 11 wherein the binding agent comprises a detectable substance, or it binds directly or indirectly to a detectable substance.
- 15 40. A kit for determining the presence of BPH or prostate cancer in a subject, comprising:
  - (a) a known amount of a first binding agent that specifically binds to kallikrein 11; and
  - (b) a known amount of a second binding agent that specifically binds to PSA;
- 20 41. wherein the first and second binding agents comprise a detectable substance, or bind directly or indirectly to a detectable label.
42. A method for screening a subject for prostate cancer comprising (a) obtaining a biological sample from a subject; (b) detecting the amount of kallikrein 11 and PSA in said sample; and (c) comparing said amount of kallikrein 11 and PSA or a mathematical combination thereof to a predetermined standard, where detection of a significant difference in kallikrein 11 and PSA or a mathematical combination thereof compared to a standard is indicative of prostate cancer.
- 25 43. A method for monitoring the progression of prostate cancer in a patient, the method comprising: (a) detecting in a sample from the patient at a first time point, kallikrein 11 and PSA (b) repeating step (a) at a subsequent point in time; and (c) comparing levels detected in steps (a) and (b) or a mathematical combination thereof, and thereby monitoring the progression of prostate cancer.
- 30 44. A method for assessing the potential efficacy of a test agent for inhibiting prostate cancer in a patient, the method comprising comparing: (a) levels of kallikrein 11 and PSA or a mathematical combination thereof in a first sample obtained from a patient and exposed to the test agent; and (b) levels of kallikrein 11 and PSA or a mathematical combination thereof in a second sample obtained from the patient, wherein the sample is not exposed to the test agent, wherein a significant difference in kallikrein 11 and PSA or a mathematical combination thereof in the first sample, relative to the second sample, is an indication that the test agent is potentially efficacious for inhibiting prostate cancer in the patient.
- 35 45. A method of assessing the efficacy of a therapy for inhibiting prostate cancer in a patient, the

method comprising comparing: (a) levels of kallikrein 11 and PSA or a mathematical combination thereof in a first sample obtained from the patient, and (b) levels of kallikrein 11 and PSA or a mathematical combination thereof in a second sample obtained from the patient following therapy, wherein a significant difference in kallikrein 11 and PSA or a mathematical combination thereof in the second sample, relative to the first sample, is an indication that the therapy is efficacious for inhibiting prostate cancer in the patient.

5. A method of selecting an agent for inhibiting prostate cancer in a patient the method comprising (a) obtaining a sample of cells affected by breast or ovarian cancer from the patient; (b) separately exposing aliquots of the sample in the presence of a plurality of test agents; (c) comparing levels of kallikrein 11 and PSA or a mathematical combination thereof in each of the aliquots; and (d) selecting one of the test agents which alters kallikrein 11 and PSA or a mathematical combination thereof in the aliquot containing that test agent, relative to other test agents.

10. A method of inhibiting prostate cancer in a patient, the method comprising (a) obtaining a sample comprising cells affected by prostate cancer from the patient; (b) separately maintaining aliquots of the sample in the presence of a plurality of test agents; (c) comparing levels of kallikrein 11 and PSA or a mathematical combination thereof in each of the aliquots; and (d) administering to the patient at least one of the test agents which alters kallikrein 11 and PSA or a mathematical combination thereof in the aliquot containing that test agent, relative to other test agents.

15. A method of assessing the potential of a test compound to contribute to prostate cancer, the method comprising: (a) maintaining separate aliquots of cells affected by the breast or ovarian cancer in the presence and absence of the test compound; and (b) comparing levels of kallikrein 11 and PSA or a mathematical combination thereof in each of the aliquots, and wherein a significant difference in kallikrein 11 and PSA or a mathematical combination thereof in the aliquot maintained in the presence of the test compound, relative to the aliquot maintained in the absence of the test compound, is an indication that the test compound possesses potential compound to contribute to prostate cancer.

20. A method of conducting a drug discovery business comprising:

47. 25. (a) providing a method as claimed in claim 45 for selecting an agent that inhibits prostate cancer in a patient;

48. (b) conducting therapeutic profiling of agents identified in step (a), or further analogs thereof, for efficacy and toxicity in animals; and

49. (c) formulating a pharmaceutical preparation including one or more agents identified in step 30. (b) as having an acceptable therapeutic profile.